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Manufacturing Challenges

A design engineer's guide to manufacturing challenges: finding balance between design, material & production.

Medical Materials & Technologies

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Authors:

Jake Eldridge | Manufacturing Technology Engineer | Medical Materials & Technologies
Morgan Perron | Manufacturing Technology Engineer | Medical Materials & Technologies
Abbi Johnson | Product Development Engineer | Medical Materials & Technologies
Dave Franta | Global Business Manager | Medical Materials & Technologies
Del Lawson | New Product and Commercialization | Medical Materials & Technologies

Introduction

When you first embark on a new medical device development project, manufacturing can feel like a long way off. It might be weeks, months or a year or more away, and with all that needs to happen before then, it can be hard to dedicate the time to think through manufacturing's effects on the final product. It can very much feel "out of sight, out of mind."

However, manufacturing has a significant impact on other stages of the product development process, from selecting a sterilization method to choosing the right materials. There are considerations to think about prior to kick-off to set your project up for future success.

To help you do just that, we will share some of the top manufacturing challenges a project can face and how you can address them before they develop into issues. We hope you find this to be a valuable resource on your next medical device project.

Where to start

The sooner you start thinking about manufacturing's potential implications, the more robust your device design will be. Manufacturing enters the discussion once a device idea is considered and definitely by the time of a functional prototype.

The correct time to involve manufacturing depends on device complexity. Key considerations: how many layers will the device have? Is there a stick-to-skin component? What about material compatibility considerations? What is the target cost?

Key manufacturing considerations

Original design changes are inevitable during different product development phases. Subsequent manufacturing challenges rely on your team's ability to balance considerations posed by device design, material choice and production process.

Remember the device requirements including look and function; which will influence final product specifications. Requirements are set by the product's end-use, and most often, cannot be changed. They will help you determine the capability of your process and, ultimately, select the best manufacturing process.

1 Challenge 1: Deciding to manufacture in-house or outsource production

The decision can be complicated as there are several factors to consider. You might have equipment that, with adjustments, could fulfill your process requirements. But will you have enough capacity, or do you need to purchase additional capital? What are the time and expense implications of choosing to outsource? Can your commercialization timeline be met with the resources you have, or do you need help? Also consider whether your company has the expertise and experience in the manufacturing process, as well as the ability to troubleshoot when problems arise.

Consider your company's ability to meet the equipment, expertise and experience requirements to determine future production resources in the short or long term. If your need is short-term, meaning future projects won't use the same resources, it would likely make sense to outsource the efforts. However, if you can take advantage of the additional resources in the long-term, it might be worth keeping production in-house.

When looking to outsource the work, we recommend vetting manufacturing partners based on experience, capacity and quality processes come together to meet your product's end-use requirements and industry standards. Find out what skills they have for future projects. Ask about previous experience with similar products, processes or materials. Understand the company's current capacity to meet your timeline and volume now, and whether it can accommodate future requests for a volume increase Inquire about which test methods are in place to repeatedly produce a quality product that meets relevant industry standards.

Once you have decided on a partner, maintain a robust design for manufacturability process. Be aware you will likely need to share proprietary information and having proper non-disclosure agreements in place. The more you let your partners in, the better they will be able to consult.

If you are looking for a converter partner and not sure where to start, check out 3M's network of preferred converters. As leaders in the field, these converter partners are knowledgeable, experienced and meet industry requirements.

2 Challenge 2: Managing several materials or manufacturing partners

If working with multiple materials suppliers or manufacturing partners, communication can become complex. Set up a process to make sure all partners receive timely updates throughout the entire project.

Successful communication processes include a pre-determined cadence between your team and your material supplier for potential formulation or manufacturing changes. Material changes are an expected part of the process; but inconvenient if happen unexpectedly during a project. Changes are integral to evolving the material and its capabilities and can happen at any phase, from development to maintenance.

In some instances, changes made to the material may not be noticeable and instead, a similar material that can replace it. Changes may also mean a return to the drawing board for the development team with either scenario, a robust change management plan helps both parties know what is expected for documentation, and any required verification and validation.

Finally, consider minimizing the number of partners involved. Your questions are better streamlined to fewer points of contact and less effort is spent on project management.

3 Challenge 3: Ensuring device material compatibility

Early device design ensures materials will be compatible with each other. Devices constructed with incompatible materials can fall apart prematurely or perform unexpectedly.

If your device will require multiple material layers; each layer needs to be compatible with the others and the manufacturing process. Material compatibility is determined based on layer's mechanical and chemical properties – how are they the same, and how are they different? Determine if there are potential sources of contamination from one layer to the next, and whether they exist naturally or are triggered during another part of product development, like the manufacturing process or chosen sterilization method.

When incompatibility does occur, narrowing down the cause(s) takes a thorough investigation. One way to find potential contamination sources is by running aging studies and sterilization studies to identify how materials might change when exposed to extreme temperatures, steam or other stressors they might encounter. Some compatibility issues might not be caught otherwise. Reviewing a analysis at different stages of the manufacturing process provides an effective method to evaluate device failure or material incompatibility.

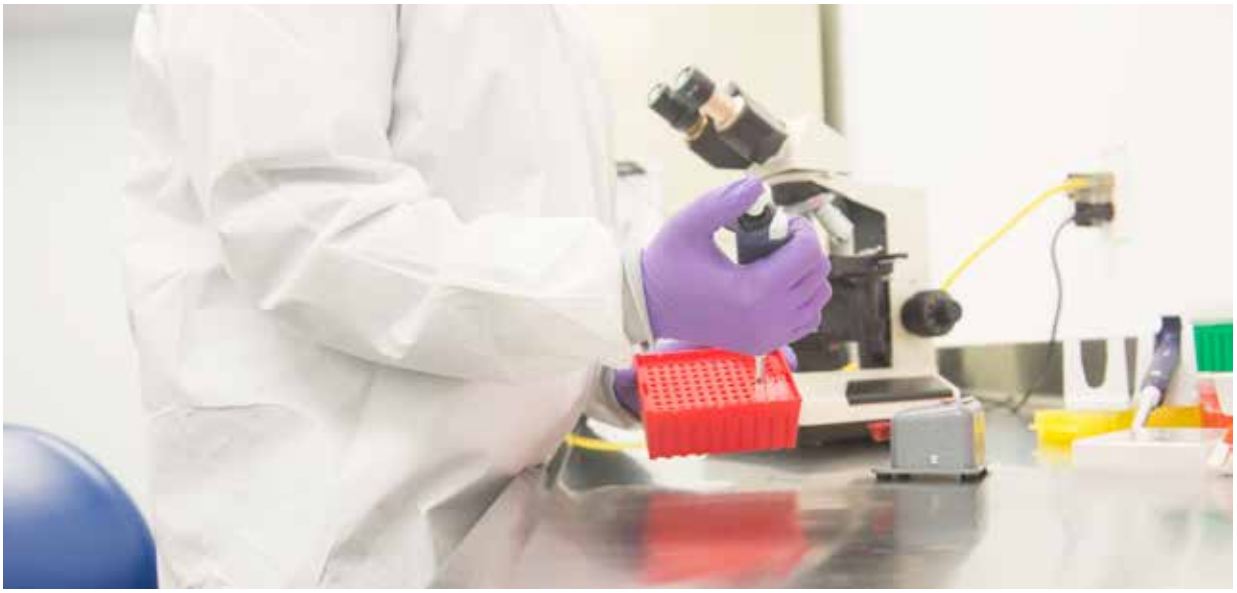
If your device incorporates a stick-to-skin component, decide what characteristics your adhesive needs to exhibit as early in the development process as possible. Adhesive selection is often an afterthought because attention is prioritized towards the overall medical device – getting it to look and function as needed. But if the stick-to-skin component doesn't work for the application, unintentionally failing, the device cannot fulfill its purpose. Have a deep understanding of your intended end-user and your device requirements to determine what role your adhesive needs to play.

Some products can incorporate recycled materials, either in an effort to save on costs or increase its sustainability. These factors can affect final product in its device form, specifically as the material ages. Some recycled materials perform as they are supposed to, but as the material ages, performance can decrease. In some microfluidic applications, for instance, there are concerns that recycled materials may exhibit unintended auto-fluorescence during product use and potentially influence test accuracy (and results). This variation in fluorescence may not be caught upon initial inspection of the material. To mitigate, ask your supplier about material composition and run aging tests to understand how recycled materials may perform in the long-term before deciding whether to use them.

4 Challenge 4: Regulating the material effects

Once the materials you have selected are compatible with one another, it is important to then ensure they are compatible with your manufacturing process. To ensuring your process is truly attuned to the product, it is essential to vet compatibility, and to test more than one lot of production-equivalent material, and raw materials.

Raw materials may not require testing multiple lots. Review the product's raw materials used and identify which ones are critical to the risk assessment material and design. Critical materials impact your product requirements to meet



regulatory, safety, efficacy, and appearance needs. They should relate directly to the design specifications of the final product. Consider evaluating more than one lot for materials designated as critical. This exercise, typically performed while doing process validation work, can also help classify your process window, as well as help troubleshoot when other issues arise.

As you would with any design, the best way to know if your device and its materials will hold up is to test a final version of your product – not just a prototype – with the desired manufacturing process. If the material cannot be processed repeatedly, you might have to look into other options. And it is better to know that sooner, rather than too far along in the development process to make cost-effective changes.

5 Challenge 5: Forecasting environment conditions

In some parts of the world, the temperature and humidity change throughout the year. In Minnesota, for instance, it is cold and dry in January but can be warm and humid in July. If your product will experience those changes while it is being manufactured or stored, the material's performance may change with it. Paper-based materials are particularly susceptible to changing with moisture. Hydrophilic

materials are also vulnerable, typically degrading over time with the presence of moisture. Incorporate different process controls and standards to accommodate the changing seasons. You can also talk with your manufacturing partner about implementing controlled-humidity manufacturing processes or rooms.

Once the device is manufactured, it is important to still consider the weather's influence on the device's materials. Even during storage or shipping of finished goods, temperature and humidity changes can alter performance. Discuss with your logistics partner whether controlled temperature or humidity requirements are needed.

6 Challenge 6: Controlling the process's effects

As alluded to in other challenges, manufacturing processes can be tough on the device and its materials. The speed, friction and pressure present during some processes can be unparalleled in other parts of the development cycle. Without special attention, these processes can cause materials to change.

When it comes to heat and other types of curing, be aware of how it may affect your adhesives. Some are heat-activated, so, unless exposing them to heat is part of your process, it is best to avoid heat exposure. Stability and aging studies will help you here, as well, in understanding how your adhesives may react.

When it comes to friction, keep in mind the role your adhesive liner plays. In some processes, you may need to remove it temporarily to accommodate the equipment or manufacturing process. If that is the case, be aware of what is happening during the liner-stripping process and what potential damage could occur to the liner. This awareness is particularly important if you plan to reuse the liner. Determine whether it will still perform as intended if it gets scratched or receives other damage. If you are not going to reuse it, but put a fresh one on, make sure the new liner is compatible with your adhesive.

Another potential liner-related issue is it fitting too tightly or too loosely. Liners that are too tight can wrinkle or cause other issues inhibiting your ability to run the material. Liners that are too loose can fall off as you are stripping it. When you cannot control the liner, you do not have a repeatable process. If the device is put into the market with an ill-fitting liner, it could spur a usability issue. For example, the liner may come off the product before intended.

It is important to schedule preventative maintenance for equipment. It will help keep your process running smoothly. Your product will help dictate what maintenance needs to be done and how often, as some materials are more sensitive than others to worn equipment. For example, a die in converting may need to be changed out more or less often because of the type of material being cut.

Check the compatibility of cleaners and anything used on the line that may not be suitable to the product's material or design. Regularly incorporated cleaning steps throughout the process help keep adhesives from gumming up equipment. This is especially important if you are running different materials on the same line. Without proper cleaning, you may need to unexpectedly stop production, which can affect the project's overall timeline and budget.

7 Challenge 7: Anticipating changes in material characteristics after sterilization

Sterilization is another consideration with a wide-sweeping influence and needs early consideration as the sterilization method can define which materials to use in projects. Some sterilization methods impair certain materials. For example, gamma radiation causes polypropylenes to stiffen and degrade.

As you are designing the sterilization process to meet your needs, consider all of your device's components, in addition to the method's temperature, duration and whether the device will be sterilized in its package. Some materials may not pose any issues before sterilization but may unintentionally interact with other materials.

A product redesign may need consideration if the device requires sterilization but does not have an available compatible method.

8 Challenge 8: Managing development costs

When it comes time to identify a reasonable price for the end product, remember to factor raw materials and other costs such as equipment and labor. To achieve the desired product quality, develop a robust and repeatable process that can run with many different operators to keep the long-term cost down.

Some development teams see another opportunity for cost-savings by using the most inexpensive material. While material price is an important consideration, performance should be the top priority. The chosen raw materials need first to meet the performance requirements to ensure your device will fulfill its intended need. If necessary, to save costs, look for lower-cost materials that can perform similarly to more expensive options. Additionally, take into account how much of a material you plan to use. If it is more expensive, but you will only use a small amount, or a small portion of the product, it might be worth using the more expensive material.

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Challenge 9:
Ensuring compatibility with producing a redesign or next generation of a product

As you build your product's initial manufacturing process, keep in mind whether you will need to redesign or produce subsequent generations of the device. If you bought equipment and tuned or built it to a specific process for the device, it can be possible to use it again. While in the cycling or design iteration phase of your current project, consider design compatibility with the existing process or co-development of scale-up for the next. How fast the development and scale-up of the next generation will also be an important consideration of whether you can use the same equipment or purchase new.

10 Challenge 10: Navigating global implications

Be aware of tariffs, sanctioned restrictions, and other international and political implications. As the economy becomes increasingly globalized, it is essential to recognize the entire value stream during the manufacturing development of both raw materials and equipment sourcing. Consider using more than one supplier when sourcing materials, especially critical raw materials, if your chosen supplier doesn't have a global presence. This lowers risks associated with any supply or shipping challenges that may arise.

11 Challenge 11: Scale-up

Testing the production process on lab equipment is important to start understanding how your product may run on the full manufacturing line, and can also produce preliminary specifications. But it is not a directly translatable process. Lab equipment is often much smaller and easier to control. When running a material at a narrow width, for instance, it can be much easier to run consistently. On a full manufacturing line, however, there may be higher variability. And until you have the luxury to run your process on a full line, it may be challenging to know exactly how it will go.

When it comes time to make the transition, take time to relearn the process controls, understand your process window and qualify the equipment. Your product requirements will help here. By vetting those against the process's variability and expected tolerance or range, among others, you will have a better understanding of what is possible. If part of the process does not meet your product requirements, is that ok? If not, explore widening your product specs or for equipment changes to help meet your needs. Other ways to reduce your risk are to run multiple lots of critical materials and have a robust design.

Conclusion:
Approaching challenges with perseverance

Manufacturing has clear implications across the entire device development process. It may take extra time to mitigate risks posed by challenges and can feel like an overwhelming task, but it all comes down to balancing trade offs and keeping your design priorities top of mind. As you approach your next device development process, keep an open mind and give the provided advice a chance. It may front-load the effort required from you and your team, but the payoff will be worth it in the long run – so continue to persevere through the process and reap the rewards of a successful launch.

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Medical Materials & Technologies
3M Center, Building 275-5W-05
St. Paul, MN 55144-1000 USA

Phone 800-584-2787
Web www.3M.com/MedTech

70-2011-7976-2