Wearable Technology:

DFMA Tips to Go to Market Faster

5 CONSIDERATIONS TO IMPROVE THE MANUFACTURABILITY OF YOUR DIE-CUT COMPONENTS

JBC Technologies

Manufacturers, no matter the industry, constantly think about simplifying production, while keeping costs down and quality high. Original equipment manufacturers in the wearable technology market are no different. The complexity of today's stick-to-skin medical devices and wearable adhesive patches makes optimizing design and production critical.

Nothing is more frustrating than designing a product, validating it using prototype volume production, and then learning that your product cannot be manufactured "at scale."

*That's where **design for manufacturability and assembly (DFMA)** comes in.*

DFMA is a principle that keeps the manufacturing process and constraints at the forefront during the design phase of a part to ensure that a device can be manufactured at high volumes at a reasonable cost. It should be as important to the design engineer and sourcing team as the manufacturer tasked with converting the concept into a finished part.

By engaging your converter early and employing DFMA principles, you can detect and solve inefficiencies before production, reducing expensive errors that could require retooling or a total redesign.

This paper highlights five key factors you'll want to review in detail with your converter early in the design phase. These factors will inform our process development recommendations, help us advise you in the material selection process, and give us insight into any potential speedbumps that could negatively impact your launch timeline, if not addressed.

FIVE FACTORS THAT INFORM PROCESS DEVELOPMENT

Successfully implementing design for manufacturing starts by asking the right questions early in the design process. Whether you are creating stick-to-skin remote monitoring patches and medical diagnostic kits, wound-care components, or cosmetic fashion tape, there are many important details to consider.

1

PRODUCT SCALE-UP SCHEDULE

- What are your three-year volume projections?
- What is your target regulatory submission timeline?
- What is your go-to-market timeline?
- At what point will you need to transition from prototype parts to production parts that must adhere to any applicable regulatory or quality requirements?
- Do you want to design the manufacturing process for high volume up front, or are you open to iterative processing methods that can evolve as your product demand increases? There is a delicate balance between tooling costs and piece price. High-volume production typically dictates higher-priced tooling–which quickly pays off in terms of lower piece price and efficiencies.

While we know it can be near impossible to predict accurate volumes for new product releases, volume projections dictate our processing decisions and help us determine where and how we source materials. Rest assured, your numbers don't need to be 100% accurate—just close enough to get us in the ballpark.

2

REGULATORY REQUIREMENTS

- Will your device require approval by the FDA or other regulatory body?
  -If yes, will it be classified as FDA Class I, II, or III?
- Do you have specific manufacturing environment requirements (White Room vs Clean Room)?
- Will your device be required to undergo sterilization at any point during its lifecycle?
  -If yes, What type of sterilization?
- Do you understand (or have a partner who can help you navigate) the FDA approval process?

Devices that require FDA approval come with additional requirements for material biocompatibility, cleanliness, and stringent manufacturing quality standards. Class III devices are subject to the most stringent regulatory control. Be sure you are working with a converter with the right certifications for your product. And, be wary of over-specifying requirements, as you may add to your costs unnecessarily.

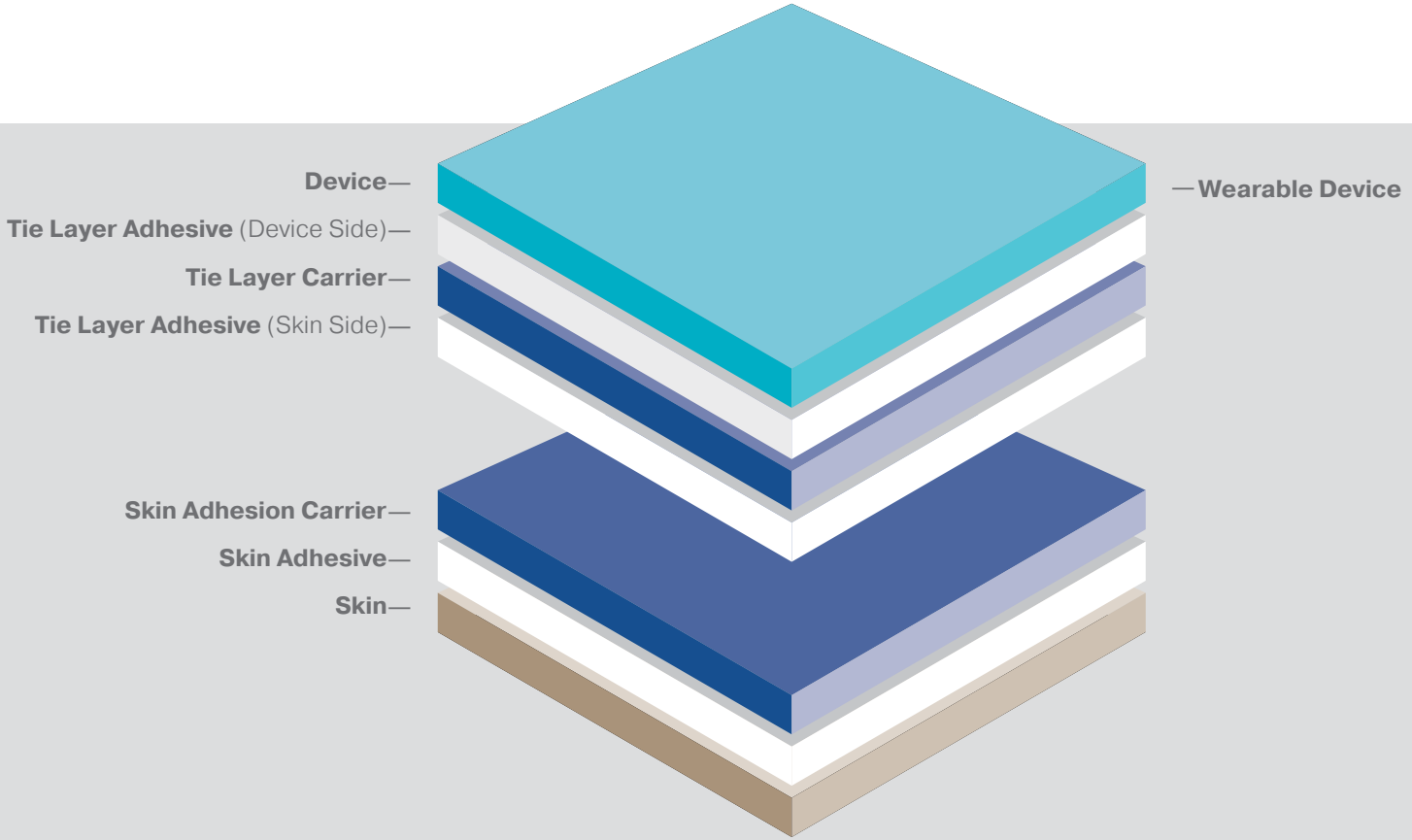
3

DEVICE CONSTRUCTION

- How many layers make up your finished device?
- What is the approximate weight of the device?
- What materials are involved besides the tape? Examples include electronic components, molded plastics, or silicone.
- Will you require your converter to do the final assembly, or will the device be post-processed?

Even if your converter is not doing the final assembly of your device, they must understand the full picture as the answers to the questions above will significantly impact material, processing, and delivery method recommendations.

EXAMPLE STACKUP



4

MANUFACTURING/ PACKAGING/DELIVERY REQUIREMENTS

Will the device require printing? If yes, are there any specific requirements regarding the ink used?

What are your tolerance requirements?

Do you need your part packaged for consumer consumption or will it undergo post-processing once it leaves our facility?

If it will undergo post-processing, will you apply your part by automated process or by hand?

Is there a benefit to you to receive your parts on a roll instead of in individual pieces?

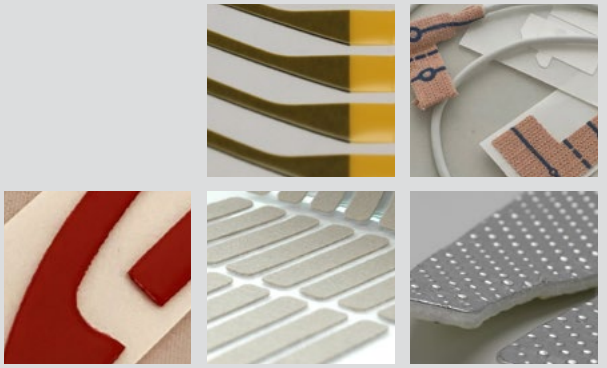
By understanding your manufacturing requirements up front, your converter can design a process and cost structure that accounts for inspection method and frequency, thus avoiding unnecessary delays, and potential cost increases when the program launches.

5

DEVICE APPLICATION

- How will your device be used?
- Is it a single-use or reusable device?
- What is the demographic of the end user?
- If the device is reusable, will you need a replaceable adhesive patch?
- Does the end-user application require the device to stay secured to the skin for short- or long-term wear?
- Does the skin-contact layer of the device need to be repositionable?
- What forces will the device be subject to? Will the application require materials that can withstand environmental stresses like moisture exposure, temperature fluctuations, and jostling?
- Will the device be applied in a clinical setting or at home by the user? While it may seem unrelated to the manufacturing process, the answer to this question can dictate the release liners we use, the part delivery method we recommend, the need for printed instructions on the device, packaging, and more.

The more your converter's technical team understands how the device will be used, the better prepared it will be to assist with material selection, provide alternative material recommendations, and recommend part delivery methods. The ability to source alternates can be important as some materials come with minimum order quantities that can be prohibitive for the early stages of a product launch.



MATERIAL SELECTION

The materials you choose can play a critical role in the function, manufacturability, scalability, and availability of your product. A benefit to working with a converter during the material selection phase instead of going directly to the material manufacturer is that while a manufacturer may limit their focus to their products, a converter can present you with a much broader set of options.

Because there are so many different variables involved with designing a product that will stick to the skin and stay stuck for the intended duration, JBC recommends that our customers perform application-specific testing as part of their material evaluation process. JBC Technologies can support this through our valued supply chain partners and rapid prototyping services.

PARTNER EFFECTIVELY

At JBC Technologies, we've seen that our customers' design responsible parties truly appreciate the perspective that a "ten-thousand-foot view" can provide. The more they know about the ins and outs of what we do, the better they understand the options available to them – and can start the design and production discussions from the standpoint of what will ultimately make a product more manufacturable and therefore more cost-effective to them.

While this paper is a good guide, we always recommend talking to a converter like JBC early in the design phase of your product, specifically if you are unfamiliar with the opportunities and limitations associated with roll-to-roll converting. We are here to help.

JBC Technologies has the quality systems, industry-leading equipment, and technical know-how to manage the complex part geometries, tight tolerances, and multi-layered constructions needed for medical device die-cutting. Contact us today to see how we can help!

Medical Converting Capabilities

- Cleanroom Converting
- High-Speed Rotary & Flatbed Die-Cutting
- Digital Cutting
- Laminating, Slitting, Sheeting, Perforating, Scoring
- Corona and Plasma Treating
- Ultrasonic Welding
- Inline Digital Printing
- Inline Vision Systems
- Multi-layer Laminates
- Island Placements

Scan to Learn More!

Material Selection Assistance | ***Design for Manufacturability Recommendations*** | ***Prototyping*** | ***High Speed Precision Die-Cutting*** | ***Kitting, Packaging & Delivery***

phone: 440.835.9037 email: Sales@JBC-TECH.com web: www.JBC-TECH.com