*The Definitive Guide to*

# ***Die-Cutting for Wearable Devices and Stick-to-Skin Products***

JBC Technologies

# Wearable technology is one of the fastest-growing markets within the medical industry . . .

. . . and shows no signs of stopping. From remote patient monitoring systems to nasal strips, pulse oximetry tapes and IV attachment patches, wearable products are pushing the boundaries of health science innovation, opening the door to new healthcare solutions.

Custom die-cutting and flexible materials converting play an important role in manufacturing various medical components, from medical-grade attachment tapes to multi-layer laminated EMI/RFI shielding for medical electronics. As simple as they may seem, the fabrication of a die-cut part can be complex, and what works in theory might not hold up in reality.

## *The Problem:*

Over-engineered designs can look great on paper but may fall apart in production. Constraints in the die-cutting process may reveal inefficiencies, complexity, or even the impossibility of production.

## *The Solution:*

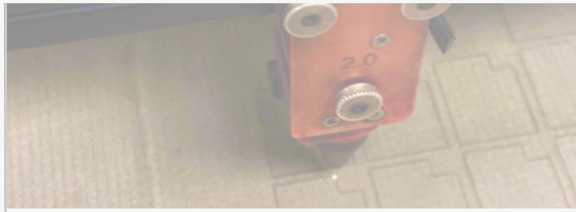
Understanding the die-cutting process from the start is crucial to designing a part that CAN be made—efficiently and cost-effectively!

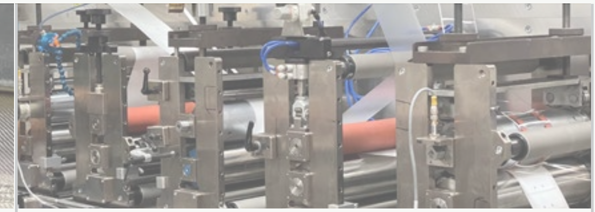
The goal of this eBook is to arm you with knowledge about the die-cutting process so you can make informed design decisions that improve the manufacturability of your next wearable device project. In this eBook, you'll learn:

- The basics of each primary die-cutting technique
- Important material selection and design considerations
- How to navigate quality and regulatory requirements
- Strategies for optimizing costs without sacrificing quality

# DIE-CUTTING 101: THE BASICS

***Let's get started with this crash course in converting capabilities:***

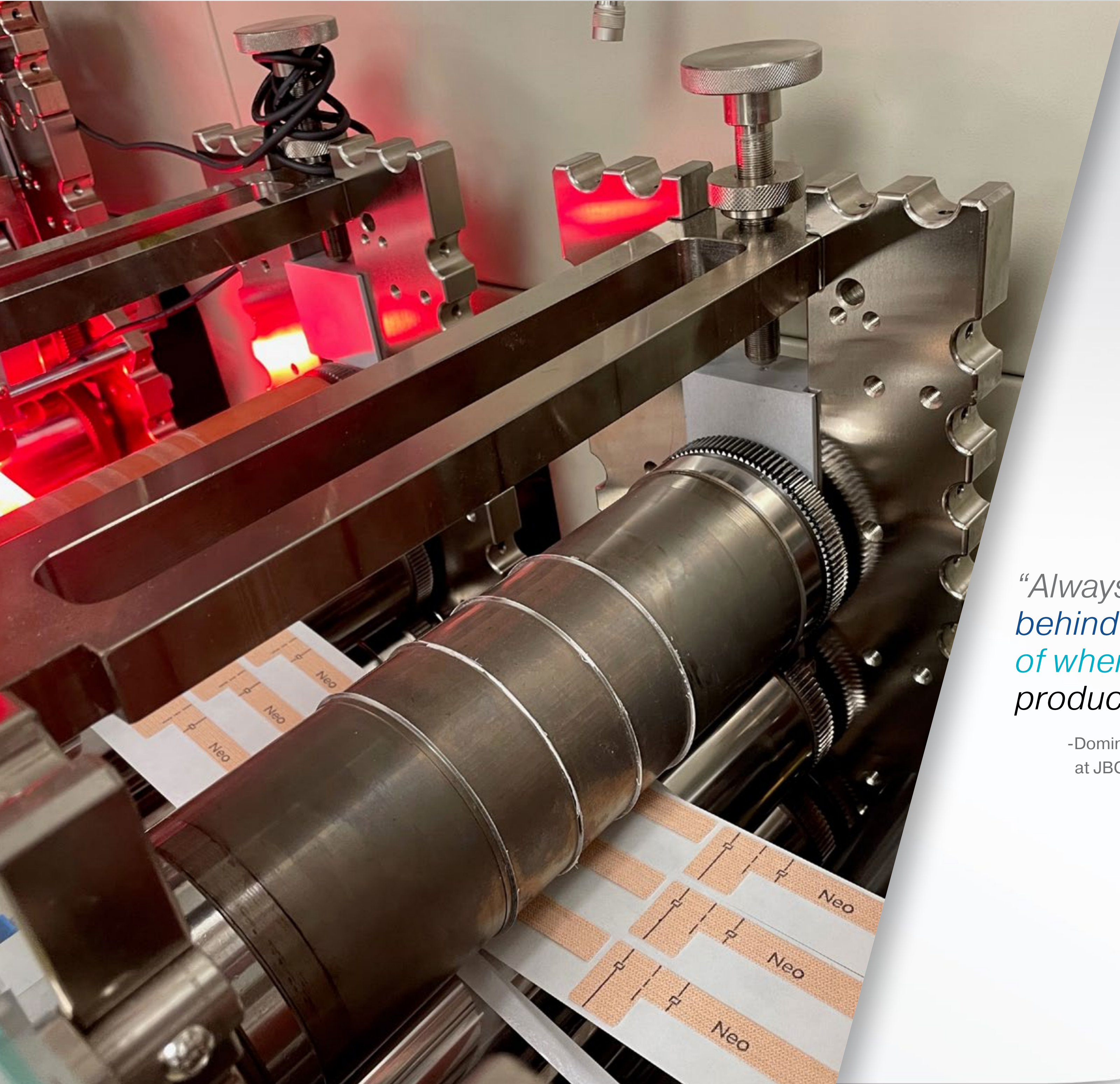




| | **Digital (Dieless) Cutting**<br>Uses lasers, knives, water or routers to cut parts without the need for tooling. | **Flatbed Die Cutting**<br>Hydraulic or electric press that pushes the die down into sheets of flexible materials. | **Rotary Die Cutting**<br>Utilizes a cylindrical cutting head and multi-station high-speed equipment. |
|---|---|---|---|
| ***BEST FOR*** | ▪ Low-volume batches for prototypes, part validation, and material testing<br>▪ Thicker, more rigid material | ▪ Thicker materials and larger parts<br>▪ Simple designs<br>▪ Lower-medium production volumes | ▪ Thinner materials (<1/8 inch thick) and smaller parts<br>▪ Complex designs<br>▪ Multi-layered designs |
| ***PROS*** | ▪ Cuts extremely tight tolerances<br>▪ Works from very small sizes up to 5x10" | ▪ Lower up-front tooling costs<br>▪ Can convert materials up to 52x72" | ▪ Multiple converting processes in a single pass<br>▪ Extremely tight tolerances<br>▪ Includes value-added capabilities (inline laminating, printing, and ultrasonic welding) |
| ***CONS*** | ▪ Inefficient for high volumes<br>▪ Cost scales steeply with volume | ▪ Less precise than rotary<br>▪ Inefficient at high volumes | ▪ Higher upfront tooling costs<br>▪ Materials must be supplied in large roll form, and less than <1/8 in. thick |

***Key Takeaway:***

Each of these methods has its niche. Together, they create a complete picture of the manufacturing process—from small batch dieless prototyping to medium-volume flatbed production, scaling up to high-volume rotary die-cutting. Designing a part that's optimized for these processes is the first step to achieving an efficient, cost-effective supply chain.




*“Always think one step behind and one step ahead of where you are in the production process.”*

-Dominic Bowlin, Engineering Manager at JBC Technologies.

# DESIGN CONSIDERATIONS

From material considerations like thickness and liner selection to post-processing considerations like part presentation, designing a wearable device that can be successfully die-cut takes careful consideration of many important factors.

**Rapid Prototyping:**

**Rapid prototyping is a very important part of the material selection process, as well as the design process as a whole. Dieless digital cutting capabilities like flash cutting allow you to quickly perform fit, form, and function testing to eliminate the guesswork from your design and material selection.**

## *Adhesive Selection*

Knowing how to select the right adhesive for your wearable device is an important place to start. Key considerations include:

### WEAR TIME

- Long-term or short-term adhesion?
- Repositionable, breathable, or flexible?
- Enviornmental Exposure?

**WHY IT MATTERS**

A long-term adhesive may need to be waterproof and could cause damage to the skin when removed or repositioned, whereas a short-term adhesive won’t have enough strength for extended wear.

### USER DEMOGRAPHICS

- Age of patient?
- Activity level?
- Body hair? (skin type)

**WHY IT MATTERS**

An elderly patient with sensitive skin will require an adhesive that’s strong enough to adhere successfully but gentle enough to not irritate the skin upon removal.

### INTENDED USE

- Device function?
- Device placement?
- Device Design (weight, rigidity)?

**WHY IT MATTERS**

A heavier, rigid wearable device worn on the arm like a continuous glucose monitor will require an adhesive with different performance requirements than an adhesive utilized for an under-eye patch.

Click here For More Information on Adhesive Selection

# DESIGN CONSIDERATIONS

## Liner
Function

The type of liner that an adhesive comes on is important when considering the feasibility of post-processing and assembly.

**THE CONCEPT:**
Adhesives are supplied in large rolls that come on many different types of liners, each having their own varying levels of tack. Liners with low tack will make it much easier to remove the adhesive components, while high-tack liners will be much more difficult.

**THE CHALLENGE:**
An adhesive may come from the supplier on a liner with high tack. This can be a problem if your component needs to be easily removed from the liner later in the assembly process or by the consumer.

**THE SOLUTION:**
A converter like JBC Technologies can perform a liner swap, switching the adhesive to a liner with less aggressive tack for easier removal later in the part's processing.

***Key takeaway:***
Share your assembly and performance goals for your finished device with your converting partner early to guarantee they can be feasibly met during the die-cutting process.

# DESIGN CONSIDERATIONS

## Biocompatibility
## & Cleanliness Requirements

Biocompatibility refers to the ability of a material to perform with an appropriate host response in a specific application, ensuring that it does not provoke an adverse reaction when in contact with biological tissues or fluids.

**THE CONCEPT:**
While biocompatibility is an important design consideration for many medical device designs, that's not always the case.

**THE CHALLENGE:**
Not all materials are inherently skin-safe. An adhesive may adhere well but trigger rashes, or a backing film may leach chemicals into the skin over time, putting a patient's health at risk.

**THE SOLUTION:**
Do your due diligence during the material selection process by collaborating with an ISO 13485 Certified converting partner to ensure that your biocompatibility needs are being met from the start.

***Key takeaway:***
Discussing your post-processing needs and the performance requirements of your final product early in the design process allows the converter to provide value-added services like liner swaps to set you up for success later in your supply chain.

# Material Thickness (tolerance)

The thickness of the material you need for your device directly affects both tolerance and machining capabilities.

### *The concept:*

The thicker the material is, the wider the machine's blade spacing must be, making it more difficult to cut tight tolerances.

### *The challenge:*

Die-cutting material that's too thick on a rotary die-cutting press can lead to undesirable defects like apple-coring. Thicker material must be digitally, or flatbed cut, which may limit production volume and affect part design.

### *The solution:*

Understand that material thickness has a direct impact on the way it can be converted as well as the converter's ability to hold tight tolerances. Knowing what's possible from a converting perspective based on your materials required thickness is important part of production planning.

### *Key Takeaway:*

There is a trade-off between the thickness of the material you select and the production volume/efficiency and part design.

## DESIGN CONSIDERATIONS

# Cut-Outs and Complex Design Features

One major way a product designer can simplify the design/production of a wearable device is by eliminating unnecessary cut-outs.

### THE CONCEPT:

Some cut-outs in a design are essential to the parts functionality, while some only add unnecessary complexity to the production process. It's important to know the difference.

### THE CHALLENGE:

Unnecessary cut-outs can lead to slower run rates and higher costs, whereas necessary cut-outs can often require very tight tolerance cutting. Without a conversation about fit, form, and function requirements your converter may not know whether there is flexibility for design for manufacturability recommendations.

### THE SOLUTION:

Work with a converter early in the design process to identify DFMA improvements such as opting for a slit or slot instead of a cut-out when applicable. When cutouts are needed, it is crucial to work with a converting partner able to cut the tight tolerances your device requires.

***Key Takeaway:***

By utilizing design for manufacturability and assembly tactics, a converting partner streamlines the production process while ensuring the functionality of your part.

# CLEANLINESS/REGULATORY REQUIREMENTS

In the medical industry, cleanliness is non-negotiable. To ensure medical devices meet the cleanliness standards for patient health and optimized  performance, the FDA classifies medical devices into three main cleanliness classifications:

### CLASS I

Low-risk devices used outside the body where the risk of contamination is low.

*Examples:*

- Stick-to-skin wearable devices
- Medical device packaging
- CGM overlay patches

### CLASS II

Utilized in sensitive locations of the body where contamination is a risk.

*Examples:*

- Catheters
- Stents
- Some surgical equipment

### CLASS III

Devices that are considered "life-sustaining" and enter vital parts of the body.

*Examples:*

- Pacemakers
- Heart valves
- Brain implants

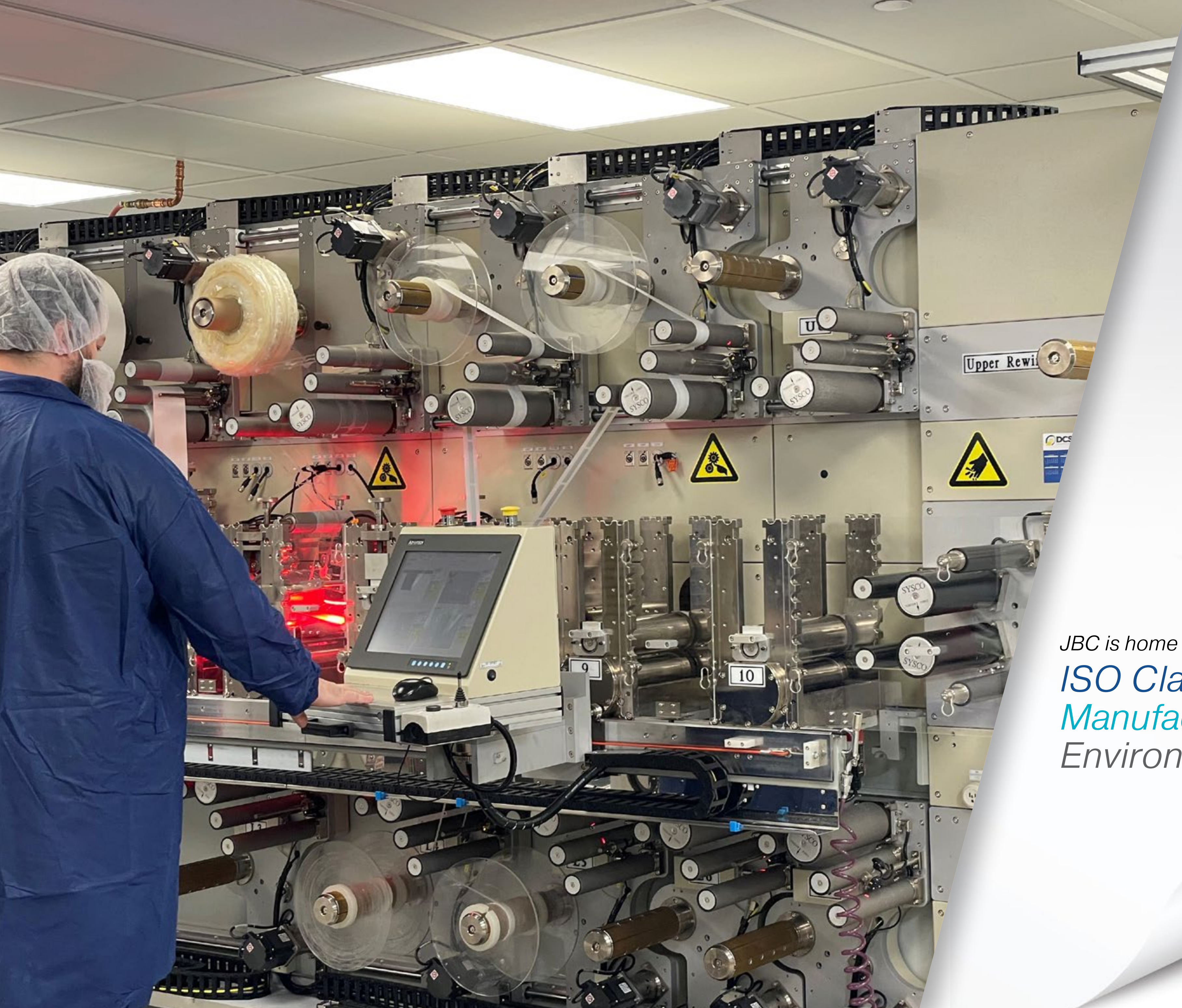
*According to the FDA, classification depends on:*

- **Intended use**
  Where will your part be used, and what is the risk of contamination?
- **Indications for use**
  How will your device be marketed, and how will these claims affect production requirements?
- **Level of risk**
  Is the risk of containment work the cost of manufacturing?

For more in-depth information, read Navigating FDA Classifications: A Guide to Cleanroom Requirements for Medical Devices

***Key tip:***

Understand and clearly communicate the cleanliness requirements of your product before it's time to put it into production to prevent any confusion or roadblocks in the production process.




*JBC is home to multiple*

*ISO Class 8*
*Manufacturing*
*Environments.*

# STRATEGIES FOR OPTIMIZING COSTS WITHOUT SACRIFICING QUALITY

## *Optimizing costs is all about optimizing efficiency.*

Every additional step of the die-cutting process adds increased complexity that can hurt the efficiency and affordability of your project. The goal of a converting partner like JBC Technologies is to simplify and optimize the design to add value wherever possible.

**Vertically integrated converting services** like slitting and laminating pass cost savings down the supply chain without affecting the quality of the product. For example, a converter can slit a master roll of material to a desired width and laminate it with a functional adhesive layer in-house, all before any die-cutting even begins.

*Part presentation is another important way that a converter can streamline production throughput without impacting quality. Optimizing the way a part is presented can have massive final assembly and downstream handling benefits.*

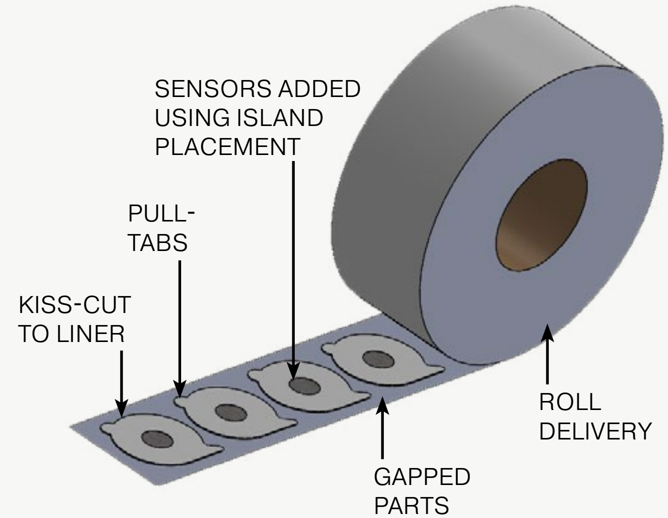
**Gapping** is the process of cutting parts without spacing and then transferring them onto a separate spaced liner. By butt-cutting adhesive parts with no gaps to maximize material yield, then transferring them onto a spaced liner for easier handling, a converter improves efficiency while reducing material waste.

**Kiss-cutting** keeps parts attached to the liner until they're needed by cutting through only the adhesive and stopping at the liner. By cutting just the material and not the liner, parts stay aligned and protected during storage and shipping, helping optimize them for post-processing.
Pro-tip: Pair with pull-tabs for maximum peel-and-stick ease!

**Roll vs. sheet delivery:** The way parts are delivered helps shape downstream handling. Rolls work great for high volumes of thinner, more flexible materials while sheets are best suited for lower-volume thicker materials. Rolls maximize automation but are only possible with thinner materials. Sheets allow for more material flexibility, but require slower, manual processing.

**Pull-tabs** are small extensions added to a part's design for easier removal and optimized post-processing. Without pull tabs, small parts can be a challenge to separate from their liners. Adding a pull-tab speeds manual assembly and consumer application-with minimal material investment. Just grab, peel, stick, and done!

**Intricate island placement** positions small, isolated functional components within a larger die-cut part. Islands are typically kiss-cut onto the material during the die-cutting process and remain embedded until the part is peeled or assembled, perfect for components like sensor contacts for proper electrical connection.




***The result:***

Lean production, optimized performance, tailored for you.

**Understanding the die-cutting process ahead of time** helps you sidestep possible manufacturing roadblocks, guiding you to a part design that can be successfully die-cut. Enlisting the help of a trusted converting partner like JBC Technologies early in the design process is the secret to avoid costly redesigns, inefficient part designs, and supply chain headaches. As an ISO 13485-certified converter with four ISO Class 8 cleanroom manufacturing environments, JBC Technologies leverages years of process engineering and materials expertise to provide custom die-cutting and materials converting solutions to the medical industry.

## *Medical Converting Capabilities:*

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

*Contact us today!*

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ISO 13485:2016 CERTIFIED