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## Overlooked Considerations for Wearable Biosensor Development

*Material selection at the design stage and effective navigation of regulatory requirements are two overlooked areas that directly impact wearable medical biosensor success.*

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The wearable medical device market is expected to reach \$245 billion by 2032, driven by technology advancements, growing demand for personalized health monitoring, and an anticipated increase in degenerative diseases and lifestyle-associated disorders. This demand represents lucrative opportunities for wearable medical biosensor manufacturers, but only the fittest will succeed in a competitive market. Material selection at the design stage and effective navigation of regulatory requirements are two commonly overlooked considerations that directly impact the success of any wearable medical biosensor. Increase your chances of success by adhering to the following best practices.

### Strategic material selection at the design stage

Material selection is crucial, and it's best to identify materials during the design stage to avoid expensive delays later in the process. Strategic material selection at the design stage helps designers manage costs and improve:

- Product reliability
- Manufacturability
- Replicability and scalability
- Patient acceptance

Follow these tips to choose the right materials for your wearable medical biosensor:

#### 1. Seek materials with an available supply chain

Supply chain issues can delay production and hinder scalability. If your desired material has a lead time of twelve months, for example, see if your manufacturer stocks an available alternative that will perform just as well.

Some manufacturers have a library of core materials that have been validated and vetted for wearable medical biosensors and manufacturing processes such as molding, heat staking, chip scale packaging, and wire bonding. Take advantage of manufacturer libraries to eliminate supply chain issues and improve reliability and replicability.

#### 2. Choose materials that require minimal production time

Production time is a vital consideration that affects manufacturability, scalability and costs, and material selection often has significant influence on the time required to produce a wearable medical biosensor.

For example, a design might call for an epoxy that bonds ABS to polycarbonate and specs at 3,000 PSI. The selected epoxy might take 30 minutes to solidify and 24 hours to cure, begging the question: do you need that strength of an epoxy? The component might only require 100 PSI, and an alternative epoxy might have a fixture time of time of just six seconds — greatly reducing production time.

It's also important to consider how material selection affects production capacity. For example, ovens are required to cure adhesives, and some adhesives take several hours to cure. If you need to manufacture 50 million units, a nine-hour cure adhesive would require an inordinate number of ovens and substantial time, making it difficult and expensive to produce at volume and scale.

#### 3. Investigate biocompatibility

It's crucial to select comfortable materials people will wear and that won't cause



adverse skin reactions. In addition, some wearable medical biosensors penetrate the skin, so designers need to ensure they're safe for subcutaneous applications and meet ISO 10993 biocompatibility standards for use.

Seek materials that have already been vetted and validated for biocompatibility to reduce the likelihood of adverse reactions, avoid costly redesigns, and increase the chances of regulatory approval.

#### 4. Consider environmental conditions

It's easy to overlook how environmental conditions impact cost and manufacturability, but it's an important consideration for material selection.

For example, an adhesive that relies on moisture at atmospheric conditions to cure could create significant process variability between seasons and locations. The adhesive will cure differently in summer when it's hot and humid than in winter when it's cool and dry. It will cure differently in Costa Rica than

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it will in Minnesota. If you must use such an adhesive, you'll likely need a controlled environment or clean room to manufacture the product, which will add costs to maintain the ideal environmental conditions.

A better solution would be an adhesive with a light cure component, which eliminates dependency on environmental conditions, improves replicability and manufacturability, and reduces overall costs.

### **5. Be willing to make trade-offs**

In a perfect world, wearable medical biosensor manufacturers would have a never-ending supply of their preferred materials. In reality, you need to be willing to make trade-offs.

For example, you might want to use a miniature microprocessor in your design, but the component isn't readily available in the supply chain. If you select a slightly larger component that still fits and works, you're trading off a little size to get access to available materials without long lead times. If availability increases for the smaller component, you can change your design later. It's not always easy, but in some cases, you can make the change without significant costs and regulatory hurdles.

Digging deeper into material selection can vastly increase your chances of success. Rather than selecting the first material that will work, designers would be wise to speak to material experts, whether internal at their companies or external at manufacturing partners. Experts can help designers compare options for high performance, lower cost materials that are readily available and manufacturable for replicability and scalability.

Experts can also help vet cutting edge materials, which are necessary for the field to advance, but typically better left for technology development environments

rather than products that need to be released within a year.

## **Regulatory requirements of next-generation devices**

There are three primary constraints to crafting a submission that earns regulatory approval in the global wearable medical biosensor market:

- Stringent regulations
- Complicated reimbursement policies
- The rate at which rules adjust to new technologies

The public expects the FDA to understand how wearable medical biosensors are used by consumers and to verify that they are safe and effective, and it's the onus of the device manufacturer to clearly demonstrate use, safety, and efficacy in its submission.

Regulations continue to evolve as consumers become more reliant on wearable devices such as smartwatches and other sensors that claim to monitor heart rate, blood pressure, blood oxygen levels and other biomarkers — especially when medical professionals rely on them for diagnosis. Experts expect regulations to become more stringent as new information, risks, and safety concerns are identified through use, evidenced by recent FDA scrutiny over inaccurate pulse oximeters.

Currently, most wearable medical biosensors require 510(k) regulatory clearance. The following tips can help you craft submissions that earn approval from regulatory bodies.

### **1. Seek a predicate device that enables the fastest path to clearance**

Earning 510(k) clearance requires showing substantial equivalence to a predicate device that has already earned market clearance, so seek a predicate device that enables the fastest path to clearance. That doesn't mean the predicate device needs to be identical,

but the more closely you can match your device to an existing device, the faster and easier it will be to earn regulatory clearance.

If there is not a clear predicate device, manufacturers can formulate a strategy to submit a De Novo request, which classifies the device as having low to moderate risk without a substantially equivalent device.

Note that some products are classified as screening tools rather than definitive diagnostic tools. The advantage to this approach is that it reduces risks — the device is a precursor to an existing approved standard diagnostic test, so approval may be easier to obtain. The disadvantage is that it's more challenging for payers to get reimbursement for screening tools versus diagnostic tools.

Though reimbursement doesn't affect approval, it does affect marketability. If you can show that a device can prevent more costly interventions, it's probably going to receive more favorable reimbursement decisions.

### **2. Implement robust design and process controls**

A robust design control procedure is the foundation to producing properly executed and documented validation. It's vital to clearly define:

- Design inputs: What and how the biosensor will be measuring and monitoring
- Expected design outputs: How the biosensor readings will be recorded and reported for the user's interpretation

It's also important to review your device from a usability perspective, which may include human form factor testing, and to conduct Failure Mode and Effects Analysis (FMEA). FMEA reviews your device from a risk perspective, identifying potential failure modes, the likelihood of failure, and the severity of its impact on

the user. With FMEA, you can mitigate identified risks to reduce the chance of failure and harm, and you can ensure manufacturing processes are repeatable, reliable, and will yield the highest quality products.

Once in the manufacturing stage, a good design control process requires continuous monitoring of product performance and making controlled changes to address any quality or unforeseen design issues to ensure the product remains safe and efficacious for the user.

### **3. Support claims with validation**

Companies tend to overlook statistically valid data to support all claims and demonstrate clear compliance with all applicable standards. The key to successful validation is clearly documenting the design inputs and expected outputs and showing how each aspect of the design was tested to prove it meets the intended requirements.

In most cases, validation needs to show the device accurately and repeatedly measured a known vital biomarker under different use conditions within a given confidence interval. Validations assure the manufacturing process is robust and predictable from a statistical perspective, so be sure to eliminate any gaps or improper approval of validation protocols and reports.

### **4. Provide clear documentation and labeling**

One of the most common reasons for denial is not providing enough sound data to support product claims. Increase your chances of approval by presenting data with robust documentation that

demonstrates a clear understanding and appreciation of the regulations. If you're going the De Novo route, it's also important to demonstrate how the device is novel and effective.

### **Documentation tips**

- Substantiate all claims with quantitative data when applicable
- Link test data that demonstrates compliance with applicable standards
- Remove any marketing bias or sentiment
- Ensure the submission is easy to understand and clearly shows how validations were planned and executed
- Adhere to the submission structure guidance defined by the regulatory agency
- Ensure all documentation is grammatically correct and follows best practices for test reports and protocols

In the submission summary, succinctly define the following:

- Product description
- Intended use
- Predicate device (if applicable)
- Non-clinical and clinical test conclusions

In addition to documentation, ensure products have proper labeling, including all required contraindications and warnings.

Always respect the submission process, and never be combative with reviewers. Instead, display professional confidence in the product and the documentation submitted to demonstrate the device's safety and efficacy.

It's helpful to have a good history of Quality Management System inspections

and audits. Often, new companies receive warning letters due to deficiencies found during inspections, which can cause 510(k) submissions to be delayed or denied. Working with a manufacturer that has a good partnership with the FDA and understands and respects regulations improves your chances of a clean, timely review and clearance.

As the wearable medical biosensor field grows, so does the competitive landscape. In many cases, material selection and adherence to regulatory requirements will be the difference between devices and programs that fail and those that earn approval and achieve market success.

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