Intricon
MICROMEDICAL TECHNOLOGY

WEAR IT WELL

Dave Liebl, Chief Commercial and Technology Officer, Intricon, highlights the main challenges for designing wearable devices.

Medical biosensors represent lucrative opportunities for innovative companies to disrupt and lead a market destined for growth. Wearable medical devices are an exciting frontier for startups and OEMs, but there are significant obstacles to the commercial viability of any device.

There is a need to take an approach to medical biosensor development that accounts for manufacturing, quality, and cost controls — early in the design process — to not only meet regulatory requirements but also enter the market with a commercially viable product.

Consider these key wearable medical device challenges and solutions:

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1: *Cost and Commercial Viability*

Designers often wait to consult manufacturers until they're ready for production quotes. At that advanced project stage, manufacturers are constrained by the design concept. They must find a way to manufacture the device to specifications, but those specs might not be the most efficient or cost-effective. Changes are limited only to those required for production feasibility, not those that could enhance the product or manufacturing process.

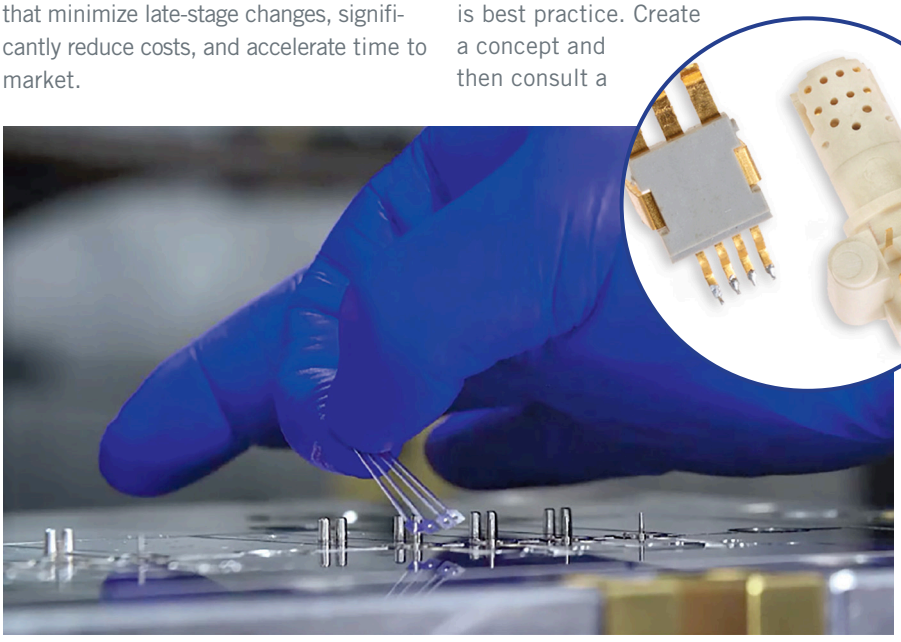
If manufacturers are consulted earlier in the process, they can recommend adjustments that minimize late-stage changes, significantly reduce costs, and accelerate time to market.

The need to scale production volumes influences cost and commercial viability. You must be able to design and manufacture a product that will hit cost targets at scale. Whether you design ten, 100, or 1,000 workable parts, success lies in your ability to sell it profitably at scale at prices the market will accept.

2: *Manufacturability*

Designers sometimes overlook the value of consulting with manufacturing experts, but working with a proven and trusted manufacturer from start to finish is best practice. Create a concept and then consult a manufacturer to complete a Design for Manufacturing (DFM) review. Lean on manufacturers and stay open to suggestions and modifications. Proven manufacturers know the best way to execute the design vision efficiently cost-effectively.

With medical wearables, a manufacturing expert can help designers understand limitations and opportunities, especially as demand increases to make components smaller without sacrificing structural integrity and functionality. For example, connectivity is crucial for many medical biosensor devices, so designers often want to encapsulate antennas, magnets, and other components in plastic. However, that isn't easy to do without affecting functional integrity. Plastic molding involves high temperatures and pressures that shift components around and reduce the functionality of magnets in electronics.



There are better ways to encapsulate an assembly, but designers aren't always aware of the manufacturing options. Overmolding is a good example. Think of an Easter egg with two halves: you can put anything inside, and the egg will protect it. With overmolding, a base component (called a substrate) is molded and allowed to cure and then, a second layer is molded directly on top to create a single, solid piece with a hermetic seal.

3: *Clinical and Regulatory Requirements*

The global biosensor market is constrained by existing and evolving regulations, complicated reimbursement policies, and slow adjustments to new technologies. A National Institutes of Health time-to-market analysis found that the main bottleneck is the clinical trial stage, where failures are rooted in insufficient design, poor understanding of user requirements, and lack of testing early in the development process.

Knowing the device's classification and researching regulatory guidance and precedents is vital. However, that can prove challenging when real-life requirements often extend beyond documented rules and include the experience of precedents and related submissions. An experienced partner can help develop the regulatory strategy and craft the submission to earn FDA approval. It might seem like an extra step, but it's far more cost effective to solve potential issues during the design stage than to re-engineer after FDA denial.

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