Providence Enterprise
Full-Service Global Contract Manufacturing

10 CRITICAL ERRORS

In the Manufacture of MEMS-Enabled Medical Devices

Microelectromechanical systems (MEMS) sensors are the backbone of connected (IoT) medical devices. Their mechanical workings detect physical stimuli such as motion, light, or sound, which is interpreted by the system's software.

Medical device manufacturers are actively harnessing MEMS to add capabilities or reduce the size and weight of their products. Unfortunately, many of them are also making errors that rack up costs, delay launches and even remove their devices from the shelves altogether.

Here is a list of mistakes that put MEMS projects at risk:

1 Incorrectly assuming that your product is a medical device

Not all devices that promote physical healing are "medical". A light therapy mask that promises to treat acne may be considered a medical device, while one that claims to reduce skin redness may fall under the cosmetic device category.

Why does correct classification matter? Because regulatory bodies such as the FDA demand a much longer, more rigorous approval process for medical devices and there is no upside to going through unless strictly necessary.

Assigning the wrong class to your medical device

Depending on level of risk and benefit to users, medical devices fall under three different categories (Class I, II, or III). A Class I devices poses negligible risk to users so are generally exempt from regulatory processes. At the other end of the scale, the higher-risk of Class III devices is balanced out by their capability to enhance or sustain life.

Incorrectly assigning a Class III product (for example, a cochlear implant) as Class II means the team is unaware of the full list of restrictions to processes, protocols or materials outlined by the FDA.

Weighing tolerance against manufacturability

How much physical impact can your product withstand without being rendered inoperable because the radio frequency (RF) range shifted or the casing cracked? What is the risk of device wires short circuiting and either stop functioning or worse, cause a fire?

The effective manufacture of MEMS-enabled devices requires consideration of several tolerances, including software-related, physical, and electrical. Only then can you be certain that your perfect design will survive production processes and use.

Not involving all disciplines in design reviews

Getting the design right means checking for absolutely everything that can go wrong. In other words, it requires scrutiny by your full team of experts. Leaving anyone out could result in significant oversights, such as components that don't fit together, bottlenecking changes to the production schedule, or falling off track for sustainability goals.

Failing to conduct design reviews

Getting things right at the design phase is the best way to de-risk all steps that follow, from production to testing to compliance to shipping to user support. Design reviews catch flaws while the device exists in purely digital form, when corrections can be made more easily than at any other stage.

Skipping medical proof of concept

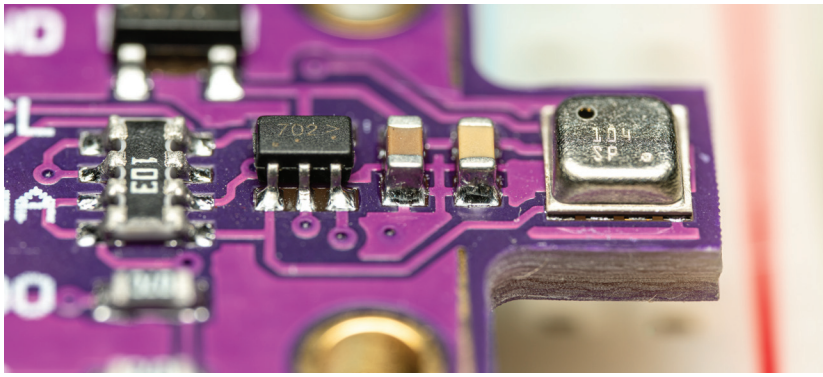
Testing an exact, fully functional replica of your device enables your team to catch any final errors in design or manufacturability errors that might stall production. Plus, certain medical device categories require you to submit between one and several hundred working prototypes to the FDA in order to get certification.

Overlooking the importance of usability

No matter how technically effective your device, it will lose out to the competition if your target demographic can't use it. This oversight is common in devices for the elderly. Users become frustrated when operating a new device requires more strength, dexterity, or tech-familiarity than they have.

Betting all your money on paper descriptions

Whether a component manufacturer sends you detailed pages or a short list of specs, numbers alone are no guarantee the component will work with your device. While the datasheets contain useful information, your team must check the actual component itself to ensure that it will fit into and function within your product's architecture.



Discounting what happens between your factory and the shelf

Your foresight created a device that could withstand the stresses of manufacturing, so it would be a shame to damage now, before it reaches the customer.

A product is most likely to be vigorously shaken, jolted, or exposed to various elements during shipping. In addition to cushioning your device against physical impact, packaging may be required to shield your device from moisture, contaminants, or even UV rays.

Not involving your CM

To diminish any possibility of mistakes, you want to put your full team in a room together at the earliest opportunity. Your contract manufacturer (CM) is part of that team. The right CM will have the added insight that comes from years of experience in MEMS and medical device manufacturing. They also support efficient coordination and communication between disciplines, and proactively propose any alternatives that will benefit you, your device, and the overall process.

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Talk to us

about how we collaborate with your team to de-risk your design, clearing the path for your MEMS-enabled medical device to sail smoothly through each stage of the production cycle.

About Providence Enterprise

Providence Enterprise is a Hong Kong contract manufacturer with manufacturing in China & Vietnam. We specialize in electronics, electro-mechanical assemblies and high-volume disposables. We are FDA registered and ISO 13485, ISO 14971, ISO 14001, ISO 27001, IATF 16949, and ISO 45001 certified. Our capabilities include fabricating tooling for silicone rubber and injection molded plastics, clean room injection molding, electronics, clean room assembly, and sterilization.

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