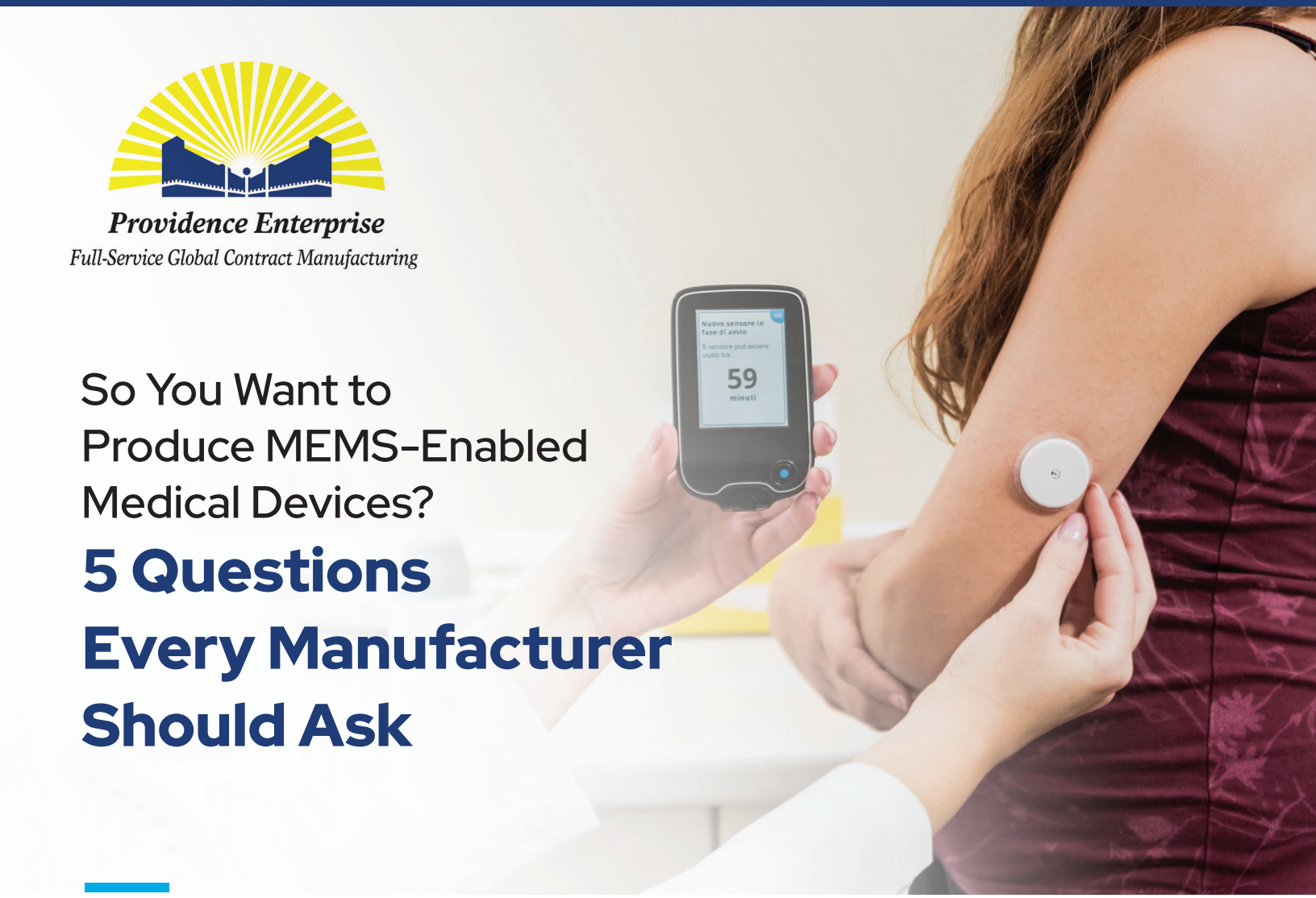
Providence Enterprise
Full-Service Global Contract Manufacturing



So You Want to Produce MEMS-Enabled Medical Devices?

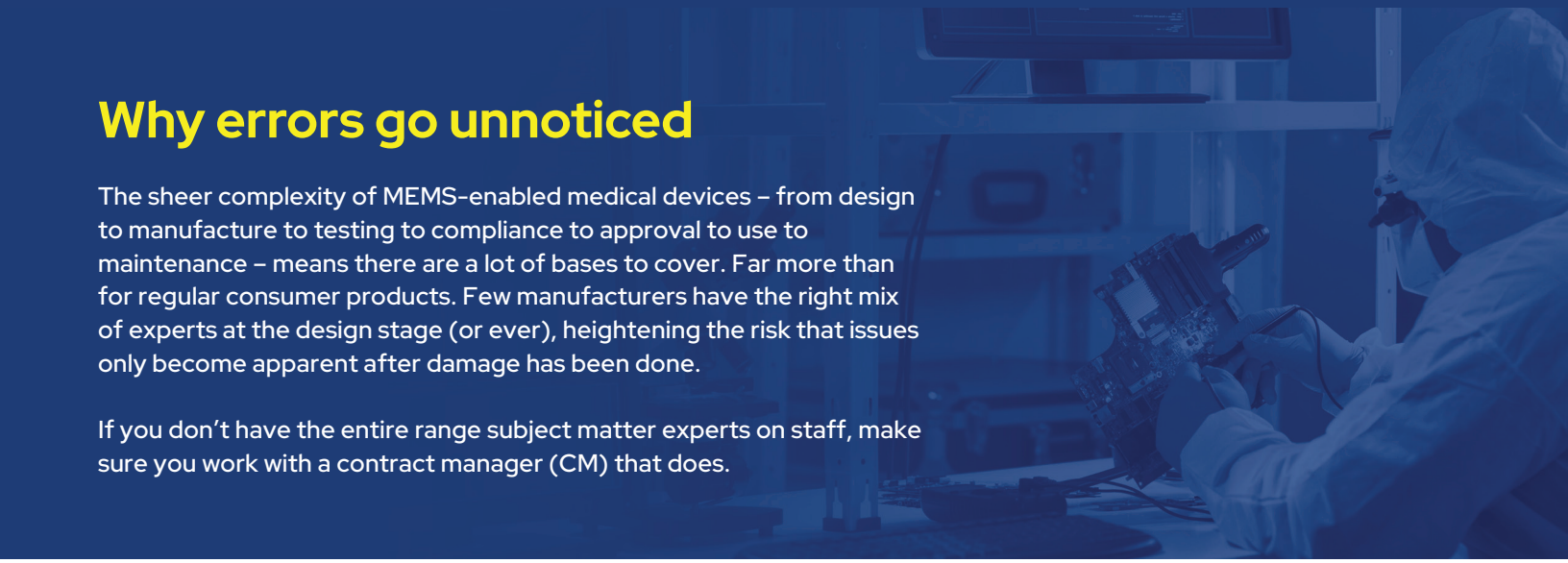
5 Questions Every Manufacturer Should Ask

It turns out that your perfect design is not so perfect after all. Frail microelectromechanical systems (MEMS) are damaged during assembly, rendering them ineffectual. Or end users give it terrible reviews because it's too bulky, difficult to operate, or requires recharging every couple of hours.

The best time for bad news

Decisions made at the R&D phase determine everything. From the quality, durability, usability, and total cost of ownership (TCO) of your medical device, to how well it performs during testing and how quickly it reaches the market.

While there is no good time to discover errors, the easiest time to fix them is when your MEMS-enabled devices are still designs and in purely in digital form. Far better than having your product languishing in warehouses because you miscalculated how long it would take to get FDA approval. Or tossing out entire batches because a flaw that resulted in a product recall.



Why errors go unnoticed

The sheer complexity of MEMS-enabled medical devices – from design to manufacture to testing to compliance to approval to use to maintenance – means there are a lot of bases to cover. Far more than for regular consumer products. Few manufacturers have the right mix of experts at the design stage (or ever), heightening the risk that issues only become apparent after damage has been done.

If you don't have the entire range subject matter experts on staff, make sure you work with a contract manager (CM) that does.

Don't assume, ask!

While the right CM will immediately reveal risks and propose ways to eliminate them, not all are that proactive. Avoid costly mistakes by taking the reins. **Ask these questions:**

1

What ideas do you have for making our device more ergonomic, lighter, more efficient, or more cost effective to produce?

A partner CM is just that; a partner who is fully invested in helping you achieve your goals. Often this means they won't merely take your design with a nod. They collaborate with your engineers and propose refinements, whether it's a more suitable MEMS, fitting pieces together differently, or making the interface more intuitive.

2

What battery or power source would you recommend to best fulfill our specifications?

Your partner CM will propose options to best meet requirements for performance, longevity, price, and weight. They will also take the initiative to recommend alternate components, sensors and machine learning software that consume less energy.

3

What MEMS would best support improvements to future iterations of our product?

The right CM partner assumes they are with you for the long haul. In addition to new materials, more efficient power supplies, improved tooling, etc., they will propose MEMS that can be used and/or easily upgraded in future iterations.

4

Have we over-designed for our target market?

Say your end-users all agree that Ferraris are cool. Now say they have a new job and need a vehicle for their daily commute. Would they wait until they could afford a luxury sports car? Or would they buy a model they could start driving right away? A partner CM will ask the tough questions about whether MEMS-enabled features are necessary or merely trendy… and likely to hamper rather than improve sales.

5 How do you minimize the impact of offsets on miniaturized systems?

While machining offsets are to be expected, the right CM will know what tolerances the device can handle to keep offset shifts to an acceptable minimum. To ensure that the device will perform as expected, your CM will also re-calibrate the board after soldering.

And that's just the **beginning**

Of course, this is a non-exhaustive list. You will want to ask your CM about the most efficient, low-maintenance tools for your specified volumes, and about protecting your devices' effectiveness from physical impact that is inevitable during manufacturing, shipping, and usage. You'll want them to warn you if they see anything in your design that might delay FDA approval.

The point is that you will want to work with a CM whose multi-disciplinary team actively participates in, or better yet, initiates conversations about possible improvements.

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Learn more about how we work with your team to de-risk your medical device's journey to and success in the market.

Contact us today.

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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