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Here’s why passing an FDA exam is so important for small caps like Compumedics

Health & Biotech

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It goes without saying getting certified by the Food and Drug Administration (FDA) helps a biotech or medtech enter the American market. But there’s more to it than that.

The latest company to obtain approval from the American regulator was brain scanning device maker **Compumedics (ASX:CMP)**.

Its devices are more powerful than traditional scanners because they use very sensitive magnetometers, which record magnetic fields by naturally occurring electrical currents too fast for conventional technologies to pick up.

It’s known as Magnetoencephalography, or MEG for short. While we are a long way from curing neurological disorders like dementia and autism, MEG could potentially detect these earlier.

Yesterday the market gave a warm welcome to the news, driving shares up over 25 per cent.

#1 device market in the world

Compumedics founder Dr David Burton told *Stockhead* it was indeed a big step.

Prior to obtaining the FDA’s blessing, companies can only sell products for specialised research via an investigational device exemption (IDE). Now Compumedics can sell its products in the broader market.

“As you can imagine it is a big milestone,” he said. “The US is the number one device market in the world particularly for sophisticated brain systems.

“It’s a world first for neuro-functional brain scanners with many functions not handled as well by MRI scanners, such as epilepsy.

“It also steps us into selling top-end systems that you see in major hospitals. That’s a shift from only doing it for specialised research.

“Now that it’s approved we can sell it on the pipeline we’ve been juggling but not been able to [fulfil].”

Made it in America? You can make it anywhere

The FDA is the most difficult body in the world to obtain approval from. Dr Burton stressed it was not necessarily pickiness but professionalism on the American regulator’s part.

“The US FDA is arguably the most sophisticated and most professional and well established body for review and clearance of sophisticated drugs but also scanning devices,” he said.

“This would be the most comprehensive or sophisticated submission we ever submitted.

“They’ve provided extraordinary thorough but highly professional scrutiny of the product. We’ve been working to provide substantial evidence to prove this is a clinical product.”

Now that Compumedics has gained America’s blessing, the Dr Burton (who has been there the whole journey having founded the firm over 30 years ago) believes his firm can make it anywhere.

In fact, that’s why he went to the FDA first.

“Our strategy was to go for the greatest scrutiny and most respected clearance which is by far the US because of its experience, depth and thoroughness of the organisation,” Dr Burton said.

“Each country has its own clearance process but some generally have a process based on already existing FDA standards. Most of the tests, electrical interference and efficacy of measurement are already a part of [FDA tests].

“So our data will be submitted to the countries but its already been prepared for the FDA.”

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