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WHEN INNOVATION MEETS GROWTH



THE BUSINESS OF MEDTECH

How to Select the Right International Market for Your Medical Device

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How to Select the Right International Market for Your Medical Device

When founders show me their international plans, there is often a map with a lot of flags on it. I understand the instinct, because the need for good medical technology is everywhere and every country looks like an opportunity from a distance. But international market entry for a medical device is expensive in time, money and attention, and a small company can usually do only a few countries properly at once. Choosing which ones, and in what order, is one of the most important commercial decisions a young company makes.

I have worked on products that reached customers in 117 countries, and I have learned that the right first market is rarely the biggest one or the most exciting one. It is the one where the clearance you hold, the money that pays for care and the people who will actually sell for you all line up. This is where a phrase I learned nearly 25 years ago from a consultant makes the most sense: make friends before you need them. It is also where Synergen can help, because we already have the friends!

Start with the clearance you already hold

The first filter is regulatory, and it is the one founders most often leave until too late. Every market has its own registration process, and some of them take far longer than anyone expects. If your device already has an FDA clearance or a CE mark, it makes sense to look first at the markets that accept or rely on that clearance, because sales can begin sooner while longer registrations run in the background. Remember, though, that outside the USA an FDA clearance is only the start of the process, and today it is becoming much harder to enter many countries, because local registration is more demanding than ever.

I also encourage companies to build one master regulatory file from the beginning. When the core documentation is kept in one place and kept current, each new country becomes a gap analysis rather than a completely new project, and that changes the economics of entering the third, fifth and tenth market. Many years ago, on behalf of a company I represented at the time, I published a notice on LinkedIn looking for a Chinese regulatory expert with experience of submissions to the Chinese authority, because it was clear that some markets simply cannot be approached without real local regulatory knowledge. That is worth knowing before a country goes on the list, not after.

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Who pays for care in your target market

The second filter is money, and specifically whose money. A device that is reimbursed in one country may have to be paid for out of pocket in another, and that changes everything about price, positioning and the speed of adoption. On a trip through Southeast Asia in 2024 for a Synergen client, I noted that there is very little private pay in Thailand, and in Vietnam I wrote quite bluntly in my report that the regulatory process would be very difficult and long and that price sensitivity was high. Neither observation made those countries wrong for the product, but both meant that the business model had to be designed for them rather than copied from somewhere else. As for Vietnam, I must add in retrospect that, thanks to an excellent distributor we brought on board, we were able to overcome many of those barriers, and it has become one of the best successes for that company.

At the end of that report I wrote a sentence that I now use with almost every client: we need to ask ourselves if these countries are real, viable opportunities. I asked whether there was a pricing model and a minimum volume that could make the opportunity viable for all parties. I asked which medical devices had already succeeded there, and in what volumes. And I asked how long it would realistically take to get through regulation and then win over doctors and patients. None of those questions had easy answers, but asking them before signing anything saved a great deal of disappointment later.

International market entry depends on real demand

Need and demand are different things, and confusing them is one of the most common mistakes I see. A country can have an enormous medical need and still have very little demand for your particular device, because clinicians do not know the technology, cannot be trained on it, or cannot fit it into the way they work.

An example from my own experience in rehabilitation illustrates the point. In 2024 we ran a small telephone survey of 20 physical therapists, most of them in Bangkok, and only 15 percent of them had ever used robotic rehabilitation products. When we asked why, they talked about cost, lack of training, thin evidence and the fact that the systems could not easily be moved. The need for rehabilitation was obvious, but the survey told us that a

company entering that market would have to invest in education and training before it could expect orders. That is the kind of finding that should shape a market plan, and it cost very little to obtain.

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Can you be there in person?

The third filter is presence, and it is the one that small companies most often overestimate. Every market you enter will need visits, training and attention for years, and a distributor in a country you never visit will eventually stop prioritizing you. Before a country goes on the list, it is worth asking honestly who in your company will travel there, how often, and who will answer the distributor's questions when the time difference means your office is asleep. If the answer is the same two people who are already covering five other markets, the new country will suffer, and so will the existing ones. My personal rule for success is a minimum of two visits a year, and even better, a visit every quarter if possible, even if it is only for one day!

Preparation also differs from country to country. Some markets expect a short and precise presentation, others want to see the device working on real patients before they believe anything, and some want months of relationship building before a serious commercial conversation even begins. None of these is better than the others, but each one asks for a different kind of preparation and a different budget of time. If you cannot prepare properly for the way a market makes decisions, it is probably not your next market yet.

Using the help that already exists

Founders often do not realize how much support is available for this decision. Export institutes, economic missions in embassies, trade fairs and industry associations all hold knowledge about markets that a small company could never gather alone, and most of them are glad to share it with a company that arrives with good questions. A few phone calls before the ranking is finished can save months of travel later.

The most useful thing you can do is to turn the map into a short, honest ranking. Put each candidate market through the same questions about clearance, payment, demand and presence, choose two or three that pass, and do those well before adding more. A company that wins two markets properly is in a far stronger position, with investors and with the next distributor, than one with ten signed agreements and no reorders.

LET'S TALK

If you are trying to decide where your device should go next, I would be glad to look at the options with you. Write to me at **gary@synergenmedtech.com** and tell me about your commercialization or international business development challenges. In the next article, I explain why the USA and the EU are not always the right place to start.

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